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07/255,689 10/12/88 CASKEY

C D-5950

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187

10/23/90

☒ This application has been examined ☒ Responsive to communication filed on 8/16/90 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~days~~ from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948.                   |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.  | 4. <input type="checkbox"/> Notice of informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/>  |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-17 are pending in the application.  
Of the above, claims 9-17 are withdrawn from consideration.
2. ☐ Claims have been cancelled.
3. ☐ Claims are allowed.
4. ☒ Claims 1-8 are rejected.
5. ☐ Claims are objected to.
6. ☐ Claims are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on \_\_\_\_\_, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Applicant's affirmation of the election of Group I (claims 1-8) in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

The Prior Art supplied in the applicants' submission of the Information Disclosure Statement using PTO Form 1449, filed 7/30/90 has been considered. The reference given as DD has not been considered because the title, page number, etc. on the paper supplied does not match with the PTO Form 1449.

This application contains numerous minor errors that are either typographical errors, misspellings, or scientific omissions/errors. Although these appear to be minor, they introduce unclarities that may weaken the clear and concise description of the invention disclosed herein. The examiner requests that applicant(s) review the disclosure and amend these minor aspects to remove the errors without adding new matter. Some examples of these minor errors are:

On page 10, line 2, the word "fluorescin" appears to be misspelled.

On page 11, lines 12 and 13, respectively, the words "phosphyltriester" and "phosphyldiester" appear to be misspelled.

On page 11, line 21 and at several locations elsewhere in the specification, the word "complimentary" appears to be misspelled.

On page 12, line 30, the word "simulataneous" appears to be misspelled.

On page 13, line 6, the word "amplication" appears to be misspelled.

On page 28, lines 10-11, the result of an analysis is stated as shown in figure 3. Certain samples are discussed such as DMD carrier mother, male fetus, etc. Figure 3 does not have these samples shown, however figure 2 does. Thus, the figure number appears to be incorrectly stated in Example 3.

In Figure 1, the letter "c" to denote exon "c" appears to be confusingly repeated.

Applicant's arguments and affidavit filed 8/16/90 have been fully considered and have been deemed to be persuasive to overcome the previously applied rejections in the office action mailed 1/29/90. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are newly applied to the instant application and constitute the complete set presently being applied to the instant application.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 1-5 and 7 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited to the multiplex PCR technique disclosed using the primers cited in claims 6 and 8. In Amendment

A filed 8/16/90 on page 5, lines 21-30, applicants state that the Kogan et al. reference does not teach how to amplify at least three sequences. Applicants go on to say that the present application was the first to recognize that 4 requirements (listed as such only in the said Amendment A) are needed to practice the multiplex amplification of at least three sequences. The Examiner wishes to point out that these four requirements are not claimed nor is there any disclosure in the specification as filed as to how to design multiplex PCR assays for the general use of this technique in order to satisfy these four requirements. Thus, someone skilled in the art would not be clearly and precisely guided by the instant disclosure as to how to practice these requirements to successfully perform the multiplex PCR assay as a general technique for a variety of deletion assays. The disclosure does however disclose the specific parameters needed for the primers cited in claims 6 and 8. See MPEP 706.03(n) and 706.03(z).

Claims 6 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The antecedent basis in the specification for the primer shown in claim 6, line 14, which starts with "(1) 5'-GAATAC..." is unclear. Table 1 gives this primer as corresponding to Exon f. and starts it in Table 1 as follows: "F-TTGAATAC...". Thus, the Table 1 primer has an extra "TT" at its 5' end compared to the claimed primer. Clarification of this conflict is requested. Claim 8, line 15, shows the version given also in claim 6.

Any inquiry concerning this communication should be directed to Ardin Marschel, Ph.D., at telephone number: 703-308-0196

AM

A. MARSCHEL:am

Oct. 19, 1990



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ART UNIT 187